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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,328	07/22/2003	John McMichael	13024/38627A	6971

4743 7590 01/22/2007
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EXAMINER

HUGHES, ALICIA R

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/624,328

Applicant(s)

MCMICHAEL ET AL.

Examiner

Alicia R. Hughes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8-18, and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Status of the Claims***

Claims 1,2,4,5,8-18, and 20-24 of the subject application are pending. Applicant's arguments and amendments filed on 31 August 2006 in response to the non-final rejection filed by this Office on 27 April 2006 have been fully considered, but they are not deemed to be persuasive. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated and expounded upon, and they constitute the complete set presently being applied to the instant application, hereby making this rejection FINAL.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,4,5,8-18, and 20-24 are rejected under 35 U.S.C. 103(a) as being obvious over Frey, II et al., of U.S. Patent Application Publication No. 2003/0072793 AL [hereinafter referred to as "Frey II, et al."] in view of Beers, M.H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17th Edition, pages 1525-1539 and 1932-1933, 1999 [hereinafter referred to as "the Merck Manual"].

The rejections germane to this portion of the present Office Action as set forth in the Office Action filed on 27 April 2006 are incorporated herein by reference.

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Applicant argues that the rejection over Frey, II et al should be withdrawn, because Frey II, et al. discloses a laundry list of agents for the treatment of a laundry list of diseases, but does not teach that one of the recited agents can be used to treat a specific disease or disorder of the central nervous system, as listed in claim 1, and further, the Merck Manual does not make up for the deficiencies, because Beers does not teach or suggest the use of nerve growth factor ["NGF"] for the treatment of disorders disclosed in the invention.

Agreeably, Frey, II et al is a broad patent that discloses numerous agents to treat a number of disease and conditions. However, the breadth of the patent itself is inadequate justification for why the disclosure of the invention in the instant application is not obvious, particularly in view of the Merck Manual's disclosure that depression falls under a broad class of mood or affective disorders.

The facts are these: Frey II, et al, was a published patent application on the date to which Applicant claims priority, and Frey II, et al discloses among other things, the administration of NGF to treat diseases and/or disorders that include diseases and disorders of the central nervous system, and therefore, the administration of NGF to treat central nervous system diseases and conditions is known. In consideration of such public disclosure, Applicant "[r]eading a list and selecting a known compound to meet known requirements in no more ingenious than selecting the last piece to put in the last opening of a jigsaw puzzle." *Sinclair & Carroll Co.*, 325 U.S. at 335. More particularly, since NGF is listed in *Frey II, et al.* as an agent to treat among other things, diseases of the central nervous system, inclusive of psychiatric disorders which are disclosed in the Merck Manual, claims 1,2,4, 5, 8-18, and 20-24 are obvious.

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In consideration of the foregoing, Examiner's previous rejection of Claims 1,2,4,5,8-18, and 20-24 under 35 U.S.C. 103(a) as being unpatentable over Frey, II et al. in view of the Merck Manual is affirmed is made FINAL.

Claims 1,2,4,5,11-15, and 20-24 are rejected under 35 U.S.C. 103(a) as being obvious over Siuciak, U.S. Patent No. 5,599,560 [hereinafter referred to as "Siuciak"] in view of the Merck Manual.

The rejections germane to this portion of the present Office Action as set forth in the Office Action filed on 27 April 2006 are incorporated herein by reference.

Applicant argues that the rejection of obviousness over Siuciak in view of the Merck Manual fails, because Siuciak only teaches use of specific members of the NGF family of neurotrophins, but does not teach the use of NGF, which is a different protein for the treatment of depression and other psychological disorders. Applicant is in error.

Siuciak teaches that "[t]he neurotrophin family *includes* brain-derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3) and neurotrophin-4 (NT-4), all of which have recently been molecularly cloned and shown to be members of the nerve growth factor (NGF) family by virtue of their sequence homology" (Col. 2, lines 50-55)(emphasis added). The word "includes" implies that there are other members of the neurotrophin family in addition to the three listed, specifically. *See e.g. Mars Inc. v. H.J. Heinz Co.*, 377 F. 3d 1369, 1376 (Fed. Cir. 2004)(The word comprising is synonymous with the words including, containing, and characterized by, and all of these words are open-ended or inclusive and does not exclude additional, unrecited elements or agents).

The specification in the instant application teaches that "[n]erve growth factor (NGF) [is] a prototypical neurotrophic factor and member of the neurotrophin family ...

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(Page 12, lines 27-28), too. Furthermore, “there remains a desire to use NGF to remedy other neurological disorders ... [such as] depression, anxiety, [and] bipolar disorder” (Specification page 13, lines 19-23). Siuciak teaches that “[b]ased on the activity of neurotrophic factors, especially those members of the neurotrophin family ... applicants have discovered that the neurotrophins are useful for the treatment of depression” (Col. 4, lines 64-67).

It is unreasonable for Applicant to argue that NGF illustrates the typical qualities of neurotrophic factors and members of the neurotrophin family and then to say that the teachings in Siuciak do not make the disclosure of the instant invention obvious, because it “does not teach the use of NGF which is a different protein for the treatment of depression and other psychological disorders” (Applicant’s Remarks After Non-Final Rejection, p.7, ¶1). If NGF is a prototypical neurotrophic factor and a member of the neurotrophin family claimed to treat depression, just as the neurotrophins in Siuciak, it would go without saying that the teachings of Siuciak make the present invention obvious, particularly in view of the Merck Manual disclosure, as discussed, *infra*.

In consideration of the foregoing, Examiner’s previous rejection of Claims 1,2,4,5,11-15, and 20-24 under 35 U.S.C. 103(a) as being obvious over Siuciak in view of the Merck Manual is affirmed and made FINAL.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026.

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The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11 December 2006

ARH


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER